657—9.12(147,155A) System, site, and process requirements. An AMDS may be utilized on site by licensed pharmacies or in board-approved remote dispensing sites engaged in the practice of telepharmacy. Each AMDS shall comply with the following minimum requirements:

9.12(1) *System access.*

a. The AMDS shall automatically and electronically record drug access.

b. Drug access and information access records shall include, at a minimum, the date the AMDS was accessed, the identity of the individual who accessed the system, the type of transaction completed, and the identity of the accessed component.

c. Information access for the purpose of retrieving or reviewing any patient or drug record or data, when the access does not permit change or addition to the record or data, shall be exempt from the access record requirements of paragraph *"b"* of this subrule.

d. The AMDS shall include the ability to assign, discontinue, and change an individual's access to drugs and information in the AMDS.

e. A licensed pharmacist or appropriately trained pharmacy technician under the oversight of a licensed pharmacist shall fill and stock drugs into AMDS components.

f. A record of drugs filled or stocked into an AMDS component shall be maintained and shall include identification of the person filling or stocking the system and, if applicable, the person checking for accuracy.

9.12(2) *Dispensing and distributing.*

a. All containers of drugs stored in each AMDS shall be packaged and labeled in compliance with federal and state laws and regulations.

b. All aspects of handling controlled substances dispensed utilizing an AMDS shall be in compliance with the requirements of all state and federal laws and regulations.

c. Each centralized or decentralized AMDS shall provide a mechanism for securing and accounting for drugs removed from and subsequently returned to the system. Drugs removed from a system component but not administered to a patient shall be returned to the pharmacy or maintained in a manner that would prevent access to the returned drugs except for the purpose of returning the drugs to the pharmacy. The provisions of this paragraph regarding preventing access to returned drugs except for return to the pharmacy shall not apply, for a decentralized unit dose AMDS, to items that are too large or bulky to be inserted into the system's return bin, to items requiring refrigeration, or to limited critical care items whose inaccessibility would compromise patient care. The provisions of this paragraph shall not apply to an AMDS utilized in telepharmacy.

d. Each centralized or decentralized AMDS shall provide a mechanism for securing and accounting for wasted or discarded drugs in compliance with federal and state laws and regulations. The provisions of this paragraph shall not apply to an AMDS utilized in telepharmacy.

e. An AMDS utilized in telepharmacy shall not permit the wasting or discarding of drugs. The automated pharmacy system shall provide that any drugs removed from the AMDS component but not delivered to the patient shall be maintained in a manner that prevents access to the drugs except for the purpose of returning the drugs to the managing pharmacy. The technician at a remote dispensing site shall not accept drugs returned by a patient or patient's agent.

9.12(3) *Security and confidentiality.* An AMDS shall include system safeguards designed to prevent and detect unauthorized drug access, including access to controlled substances. System safeguards shall also be designed to prevent and detect unauthorized access to information for the purpose of modification or manipulation of patient records and prescription drug orders.

a. An AMDS shall be capable of generating reports of all drug access activity. Reports shall include, at a minimum for each drug access record, the following:

(1) Identification of the person accessing the drug or drug bin.
(2) The date and, preferably, the time.
(3) Identification of the specific drug or drug bin.
(4) Whether the drug access involved stocking, dispensing, wasting, or returning the drug.
(5) The quantity of the drug.
(6) The accessed component.

b. An AMDS shall maintain confidential patient records and information in compliance with rules 657—8.16(124,155A) and 657—21.2(124,155A).